REMARKS

Applicant's undersigned counsel thanks Examiner Lacyk for a careful and thorough examination of the application, and for the productive and helpful phone interview conducted on May 13, 2009. Herein, claim 1 has been amended to define over the cited prior art as discussed in the telephone interview. Support for the amendments can be found in Figure 1, and at paragraphs [0009] and [0011] of the published application. As pending, claims 6-9 and 33-36 have been allowed. No new claims or matter has been entered.

Reconsideration of the subject patent application in view of the present remarks is respectfully requested.

Drawing Objection

The present Office action objects to the drawings and states that the drawings must show every feature of the invention specified in the claims. In particular, the balloon at the distal end of the tubular instrument, as discussed in paragraph [0037], is requested to be shown or the feature canceled from the claim. A corrected drawing sheet is also requested.

The applicant respectfully believes that a corrected drawing is not required. As correctly pointed out by the Examiner, paragraph [0037] does disclose that the distal end of the delivery apparatus may include an inflatable balloon. Further, as shown above, allowed claim 6 claims that the distal end of the tubular instrument includes an inflatable balloon. Figure 10 correctly shows the distal end of the claimed delivery apparatus can include a balloon. Paragraphs [0045] and [0046] also references the delivery apparatus of Figures 4 and 10, and states that a balloon 112 can be located at the distal end of the delivery apparatus. As such, the applicant respectfully

believes that the drawings, and in particular Figure 10, show the claimed balloon at the distal end feature of claim 6. Because the claimed balloon at the distal end feature is shown in the drawings, and also described in the specification, it is requested that the objection as it applies to the drawings is withdrawn.

Claim Rejection - 35 USC § 103

Claim 1 is the only pending, unallowed independent claim. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6338345 ("Johnson") in view of US 6652883 ("Goupil"). US 5599852 ("Scopelianos") has also been cited to further teach an injection site in the urethra. Applicants respectfully request withdrawal of the rejection for at least the following reasons.

Herein, claim 1 has been amended to define over the cited art of the present Office action. Amended claim 1 is directed to, in part, a method for treating urinary incontinence comprising implanting a bulking prosthesis through the hole at the *external* urethral sphincter, wherein said bulking prosthesis *does not migrate* after said implanting and said bulking prosthesis allows the patient to *exercise voluntary control* over said *external* sphincter.

The present Office action relies on Goupil and Scopelianos for teaching that bulking materials can be used to treat urinary incontinence. More specifically, Goupil states "some types of incontinence can be treated by injection of a bulking agent into the submucosa of the urethra, in order to "beef up" the area and improve muscle tone." (see col. 1, lines 61-64). Goupil fails to disclose where the bulking agent should be injected, and does not teach or suggest implanting the claimed bulking prosthesis at the external urethral sphincter. Goupil also only refers to a method

of injection, rather than the claimed implanting of a non-migrating prosthesis (i.e., not flowable). Therefore, the determination of the place where the bulking prosthesis is to be implanted cannot be obtained from Goupil because it fails to disclose at least a step of implanting a bulking prosthesis through the hole proximate at the external urethral sphincter, wherein the bulking prosthesis does not migrate.

To address the claimed implanting location, at the external urethral sphincter, the present Office action cites Scopelianos, which discloses "a *similar* bulking material that is *injected* into the submucosa of the urethra at or around the *urethral-bladder junction* to the external sphincter." Scopelianos is focused on the urethral-bladder junction area, which corresponds to the *internal* urethral sphincter (the external sphincter is downstream of the junction). The internal urethral sphincter is controlled *involuntarily*, whereas the claimed external urethral sphincter is controlled *voluntarily*, and thus the non-migrating bulking prosthesis allows the patient to exercise voluntary control over the external urethral sphincter. More specifically, as shown in Figure 1, the bulking prosthesis (28, 30) is implanted *at the external urethral sphincter* (18). The bladder (12) – urethral (10) junction, as specifically referenced in Scopelianos, corresponds to the *internal* urethral sphincter (16). The claimed implanting location is at the external urethral sphincter, which is voluntarily controlled. The internal urethral sphincter, as disclosed in Scopelianos, is involuntarily controlled, and thus the claimed implant location is not taught by Scopelianos, and would also *not* achieve the claimed voluntary control.

Moreover, Scopelianos only teaches *injecting* (i.e. liquids) a *soft tissue* augmentation material having an appropriate degree of pliability. The claimed bulking prosthesis is not a liquid that is injected, and the bulking prosthesis is further claimed as a non-migrating prosthesis

(i.e., not flowable). Scopelianos also specifically teaches away from using the claimed bulking prosthesis. In contrast to the taught *injectable* material, Scopelianos teaches away from harder solid or semi-solid implants that would not migrate after implanting, and which could not be injected. For example, Scopelianos clearly states "..., due to pliability concerns, the thermoplastic and thermosetting materials that Dunn proposed appear to be too hard for use in soft tissue augmentation or repair ..." (col. 2, lines 6-10). Scopelianos goes on to state "However, these blends do not appear to be suitable for use as injectable soft tissue defect fillers, because they are too viscous to be injected through a needle ..." (col. 2, lines 17-21). As shown above, not only does Scopelianos only focus on the *internal* urethral sphincter (involuntary control), but that reference specifically teaches one skilled in the art that non-injectable materials, such as the claimed bulking prosthesis, are unsuitable for treating urinary incontinence. For at least these reasons, it is respectfully submitted that neither Goupil nor Scopelianos, alone or in combination, render claim 1 obvious. Moreover, because Scopelianos specifically teaches away from using non-injectable materials, the rejection of claim 1 as being obvious over Johnson in view of Scopelianos should be withdrawn. Accordingly, it is believed that claim 1 is allowable.

All remaining pending unallowed claims (i.e., claims 2-5) are dependent claims, and are therefore also respectfully submitted to be allowable, at least by virtue of their dependence on an allowable antecedent claim, claim 1. Since the only pending, nonallowed independent claim defines over the applied Johnson, Goupil and Scopelianos references, a Notice of Allowance is appropriate and is respectfully requested. If it is determined that the application is not in a

condition for allowance, the examiner is invited to initiate a telephone interview with the undersigned attorney to expedite prosecution of the present application.

If there are any additional fees resulting from this communication, please charge same to our Deposit Account No. 16-0820, our Order No. BUG8-44251.

Respectfully submitted,

PEARNE & GORDON LLP

By: _____
J. Gregory Chrisman, Reg. No. 58923

1801 East 9th Street
Suite 1200
Cleveland, Ohio 44114-3108
(216) 579-1700

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